



Industrial Hygiene Group
Environment, Health & Safety Division

January 30, 2003
IH-03-008

Mr. Mark Hemphill
Laboratory Registration/Select Agent Program
Office of Health and Safety
Centers for Disease Control and Prevention
1600 Clifton Rd. N.E. MS E79
Atlanta, GA 30333

**RE: Notice of Intent Not to Register Under The New CDC and APHIS Regulations
Regarding Listed Select Agents, Overlap Agents, and Toxins for The Production
Genomics Facility of the DOE JGI**

To Mark Hemphill:

The Production Genomics Facility (PGF) of the Department of Energy (DOE) Joint Genome Institute (JGI) is located in Walnut Creek, California. The PGF is currently registered by the CDC Laboratory Registration/Select Agent Program

Although the PGF is currently registered, this letter is to inform you that E. O. Lawrence Berkeley National Laboratory does not intend on registering the PGF under the new DHHS/CDC and USDA/APHIS regulations regarding listed select agents, overlap agents, and toxins (i.e., DHHS/CDC 42CFR73 and USDA/APHIS 9CFR121).

PGF is currently registered due to the broad definition of select agents under the existing DHHS/CDC 42CFR72 regulation. The PGF performs genomic sequencing of various microorganisms, including bacteria and fungi. Under the current PGF registration and select agent regulation (i.e., 42CFR72), PGF is registered by CDC to receive and transfer *genomic material* for seven select agent *bacteria* with biosafety level 1 controls. This genomic material (i.e., DNA fragments) is excised from bacterial select agents by collaborators at other locations prior to shipment to PGF and, all transfers are reported on EA-101 forms. The PGF does not have viable select agents or whole genomic select agent DNA. We registered PGF under the current regulations because 42CFR72 Appendix A defines Select Agent "Recombinant Organisms/Molecules" broad enough to potentially include (and not clearly exclude) the *genomic DNA from all select agents*. Appendix A of 42CFR72 defines "Recombinant Organisms/Molecules" broadly as "genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with disease."

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Under the new regulations (i.e., DHHS/CDC 42CFR73 and USDA/APHIS 9CFR121), definitions of select or overlap agents and toxins do NOT include genomic materials from the *bacterial* select or overlap agents that are being sequenced at the PGF. Sections 73.4(e), 73.5(e) and 121.3(c) specify that "Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms" that are select or overlap agents and toxins include "...*viral* nucleic acids..." and "nucleic acids that encode for the functional form(s) of any of the *toxins* listed..." or listed *viruses, bacteria, fungi, and toxins* that have been genetically modified. Under the new regulation, PGF does NOT work with select or overlap agents or toxins. Since PGF does NOT work with living select agent *organisms* (or modified organisms), select agent *viral* nucleic acids, nor nucleic acids that encode for select agent *toxins*, the new 42CFR73 and 9CFR121 regulations do not apply to current PGF work.

Effective 7 February 2003, we will no longer report to CDC transfer and destruction of bacterial genomic materials that were previously reported on EA-101 forms. On and after February 7th, applicable sections of the new regulations are in effect.

In summary, Berkeley Lab does not intend on registering the PGF under the new DHHS/CDC and USDA/APHIS regulations regarding listed select agents, overlap agents, and toxins. But, PGF will continue to sequence the genomic materials from bacterial agents that were previously registered under 42CFR72 in March 2002.

If you have questions, please contact me at 510-486-6218.

Respectfully,


Paul M. Blodgett, CIH
Biosafety Officer and Responsible Facility Official
E. O. Lawrence Berkeley National Laboratory

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